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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,041	12/03/2003	Samuel J. Danishefsky	2003080-0142 (SK-893-B-US	4230

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
04/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,041	DANISHEFSKY ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27, 31-58* is/are rejected.

7)☒ Claim(s) *28-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

After review and reconsideration, the finality of the office action of January 26, 2009 is withdrawn in light of the rejections below.

Claims 12 and 14 have been amended. Claims 48-58 are rejoined for examination at this time. The Restriction Requirement of September 29, 2006 is hereby withdrawn. Claims 1-58 are pending and under consideration.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/209,618, 09/614,742 and 60/150,088, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. None of the applications contemplate a multi-antigenic glycopeptide wherein each antigen is presented as a cluster, separated by amino acids not carrying a carbohydrate domain. Further, the '088 provisional application fails to provide for any multi-antigenic glycopeptide. Accordingly, the instant application will be given the effective filing date of December 3, 2003.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

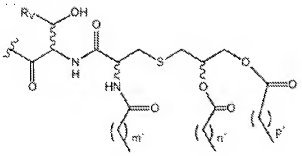
Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 is dependent upon claim 46 which requires an immunological adjuvant which is bacteria or liposomes. Claim 47 recites "QS21" as one of the species of the immunological adjuvants of claim 46. However, QS21 is a saponin and is therefore not a bacteria or a liposome.

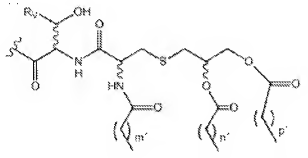
The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 and 31-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for clustered multi-antigenic constructs of claim 1 wherein the spacer is peptidic, wherein the constructs do not have a crosslinker (q=0) and which are attached to the lipid having the structure of



wherein m', n' and p' are each independently integers between 8-20, Rv is hydrogen, substituted or unsubstituted linear alkyl, branched chain alkyl or substituted phenyl or unsubstituted phenyl, including tripalmitoyl-S-glycerylcysteinylserine as an immunogenic carrier and pharmaceutical compositions comprising clustered multi-antigenic constructs of claim 1, wherein the spacer is peptidic and a carrier which is a lipid having the structure of



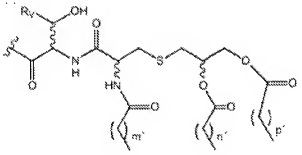
wherein m', n' and p' are each independently integers between 8-20, Rv is hydrogen, substituted or unsubstituted linear alkyl, branched chain alkyl or substituted phenyl or unsubstituted phenyl, including tripalmitoyl-S-glycerylcysteinylserine as an immunogenic carrier, and methods of treating a subject suffering from cancer and comprising the administration of said pharmaceutical composition comprising the clustered construct, wherein the spacer is peptidic and a saponin adjuvant, or a saponin adjuvant which is QS21 or GP!0100does not reasonably provide enablement for clustered constructs of claim 1 conjugated with carriers that are not the above lipids, such as KLH, polylysine, HSA or BSA, pharmaceutical compositions comprising the clustered constructs of claim 1 in combination with an immunogenic carrier which is not the above lipid, or methods of treating cancer comprising the administration of the clustered constructs of claim 1, without the above lipid and without a saponin adjuvant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The specification teaches the combination of clustered multi-antigenic glycopeptide constructs formed by units of peptides bearing a glycopeptide in combination with a spacer which is peptidic in nature to a linker or a linker which is further conjugated to a crosslinker. The specification teaches that pharmaceutical composition can be formed by linking the

clustered constructs to an immunogenic carrier such as a protein, peptide or lipid, including KLH, polylysine, HSA or BSA , or that pharmaceutical compositions can be provided which include the clustered constructs of claim 1 in addition of an immunogenic carrier such as KLH, polylysine, HSA or BSA which are not conjugated to the clustered construct and immunological adjuvants such as Salmonella Minnesota, and BCG. the specification contemplates the distraction of said pharmaceutical compositions as a method of treating cancer in patients and as a method of evoking an antibody response in a subject effective to elicit antibodies which bind with tumor cells.

The art teaches (Kudryashov et al, PNAS, 2001, Vol. 98, pp. 3264-3269, reference of the IDS filed January 12, 2004, see page 3266, second column, under the heading of "Immunogenicity of a Clustered LeY-KLH Conjugate") that administration of clustered epitopes of LeY to mice resulted in antibodies which only recognized the immunizing epitope and did not recognize isolated LeY. Kudryashov et al further teach that when the clustered LeY epitope was administered with Pam3Cys as a carrier and the saponin adjuvant QS21, antibodies were elicited which recognized LeY better than (LeY)3 (page 3267 under the heading of "Effect of Including QS21 Adjuvant in the (Ley)3-Peptide-Pam3Cys Vaccine". The specification does not teach an alternative use for the constructs which are not linked or provided with the lipid carrier



other than as vaccines against cancer. Further, the specification provides no teaching regarding the "spacer" other than those which are peptidic in nature. Based on the teachings of Kudryashov et al using a spacer which is peptidic, one of skill in the art would conclude that the properties of the conjugate could be altered in an unknown manner by using spacers which are not peptides because the immune response is sensitive to carrier structure and therefore it would

be expected that the immune response would be sensitive to the structure of the spacer as well. One of skill in the art would not know how to use the broadly claimed clustered construct which only functioned to elicit antibodies to the immunizing antigen and did not provide any cross reacting antibodies to bind to cancer cells expressing the antigen.

Claims 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643